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SYDNEY M PUGH

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EXAMINER

PREBILIC, PAUL B

ART UNIT

PAPER NUMBER

3774

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DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

09/029,872

Applicant(s)

PUGH ET AL.

Examiner

Paul B. Prebille

Art Unit

3774

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 02 November 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,2,12,23,26,38 and 47-56 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,12,23,26,38 and 47-56 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 11/2/07.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

The response filed November 2, 2007 was not fully responsive to the previous Office action because it did not provide information requested in the "Conclusions" section thereof. In particular, the Applicant failed to point out where there was support in the original specification for any new or amended claim and failed to identify any copending applications that set forth similar subject matter. Failure to comply with these requests may result in the response being deemed non-response in the future.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2, 12, 23, 26, 38, and 47-56 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claimed hydroxyapatite to tricalcium phosphate ratios lack original support from the specification in that the ratios originally provided were for sintered pure hydroxyapatite and not the hydroxyapatite stabilized with stabilizing entities as presently claimed; see page 12, line 20 et seq. of the original disclosure. The pure hydroxyapatite material is apparently a prior art material of another patent. However, there are no ratios associated with the stabilize hydroxyapatite material originally disclosed. For this reason, the Examiner

asserts that the present claims contain new matter with respect to the original disclosure.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 2, 12, 23, 26, 38, 47, 48, and 50-56 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The ratio of "at least 50:50" or "at least 666:333" tricalcium phosphate to hydroxyapatite is confusing because a ratio is a ratio and not a range. In other words, it is not clear a ratio greater than 50:50 is intended to be. It may be that the Applicant intended to state that the stabilized material is at least 50% or at least 66.6% tricalcium phosphate.

With regard to claim 47, it is unclear what the components of the ratio are.

### ***Claim Rejections Based Upon Prior Art***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 12, 23, 26, 38, 26, 38, and 47 are rejected under 35 U.S.C. 102(b) as anticipated by Ruys (article entitled "Silicon-doped Hydroxyapatite") or, in the alternative, under 35 U.S.C. 103(a) as obvious over Ruys (article entitled "Silicon-doped Hydroxyapatite") alone. Ruys anticipates the claim language where the sol-gel of Ruys is a uniform mixture of hydroxyapatite and silicone which is converted to alpha-TCP by sintering as claimed; see page 71 (the abstract), page 74, last paragraph, and page 76 (the section entitled "Silicon Addition"). Although not preferred, it was made into a material that was close to a ratio of 50:50 that is within the claimed range; see page 77, lines 15-17. The result of Ruys' process is a bulk material. Furthermore, since the material of Ruys is the same as that claimed, it would inherently be insoluble in physiological fluids and have the same resorbability and *in vivo* response as claimed because it is the same material as that claimed alpha-tricalcium phosphate; see page 72.

\*The Examiner posits that the effective filing date of the present claims is August 30, 1996 because the provisional application 60/003,157 and the earlier parent application 08/576,238 only disclosed silicon entities and not other types of entities as the present claims do. Therefore, the present claims have a later filing date because the term stabilization or the meaning of stabilization entities was broadened from the meaning it had in the parent application filed before August 30, 1996.

Alternatively, one may not consider Ruys as meeting the claim language because the disclosure of the amounts of components is not analyzed in detail, and Ruys prefers low dopant levels to avoid tricalcium phosphate (i.e. TCP) and the associated biodegradability. However, since low dopant levels are only preferred and

the concept of high dopant levels is also disclosed, the Examiner asserts that it would have been at least obvious to make higher dopant materials that would fall within the claimed range when a more biodegradable material was desired.

With regard to claim 2, the higher concentration of silicone results in primarily alpha-TCP (see page 71 of Ruys), and thus, the Examiner posits that the 50 mol% material of Ruys would inherently result in a primarily alpha-TCP material after sintering.

With regard to claim 12, the material of Ruys is the same as that claimed and disclosed, and thus, it inherently has the same solubility properties such that this claim language is fully met.

With regard to claim 26, Ruys fails to disclose the particle size as claimed even though it was disclosed as being crushed and pelletized; see page 76. However, since it was known, in the art, to crush and pelletize the same material as claimed, it is the Examiner's position that the mere selection of a particle size would have been considered prima facie obvious to an ordinary artisan because it has not shown to provide some advantage, solve some stated problem or used for some particular purpose, the Examiner takes the position that it would have been considered prima facie obvious to use the claimed particle size with the Ruys composition; see MPEP 2144.04.

In *Gardner v. TEC Systems, Inc.*, 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), cert. denied, 469 U.S. 830, 225 USPQ 232 (1984), the Federal Circuit held that, where the only difference between the prior art and the claims was a recitation of relative dimensions of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art device.

Claims 48 to 56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ruys (article entitled "Silicon-doped Hydroxyapatite") alone. Ruys discloses materials where the TCP content is slightly greater than the hydroxyapatite content; see page 77, lines 15-17. However, since low dopant levels are only preferred and the concept of high dopant levels is also disclosed, the Examiner asserts that it would have been clearly obvious to make higher dopant materials that would fall within the claimed range when a more biodegradable material was desired.

***Response to Amendment***

The declaration under 37 CFR 1.132 filed November 2, 2007 is insufficient to overcome the rejection of claims 1, 2, 6, 12, 13, 22, 23, 25, 32, 34, and 38 based upon Ruys as set forth in the last Office action because:

(1). The declarant failed to set forth facts with actual test data. In particular, the declaration failed to indicate (a) how many attempts were made, (b) the parameters used, and (c) the actual results obtained.

(2). The declarant compares the methods of making the prior art to the disclosed invention instead of the final products so the declaration is not clearly relevant to the claimed invention, that is, to a final product. Therefore, the procedures described are not clearly germane to the rejection issue. The procedures described are in the above referenced application and not set forth in the individual claims of the application. Thus, there is no showing that the procedures allegedly performed were commensurate in scope with the claims. See MPEP § 716.

(3). The actual test data was not provided so it is not clear whether the Ruys material actually differed from the Applicant's material. In other words, there is no objective evidence of the differences that are alleged to be present.

(4). The declarant is a co-inventor so he has a vested interest in the outcome of the present application.

(5). There is no clear nexus of the procedures described to the claimed invention.

(6). There is no actual proof of the procedures described.

In view of the foregoing, when all of the evidence is considered, the totality of the rebuttal evidence of nonobviousness fails to outweigh the evidence of obviousness.

### ***Response to Arguments***

Applicant's arguments filed November 2, 2007 have been considered but they are not persuasive. The Examiner has amended the rejection and addressed validity of the declaration, and therefore, the Applicant is respectfully requested to consider these items as effectively addressing the Applicant's arguments.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within



TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 or 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action if the application is not stored in image format (i.e. the IFW system) or published.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Paul B. Prebilic whose telephone number is (571) 272-4758. He can normally be reached on 6:30-5:00 M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Paul Prebilic/  
Paul Prebilic  
Primary Examiner  
Art Unit 3774